Data Demonstrates Durability of Medtronic's VenaSeal Closure System, a Non-Tumescent, Non-Thermal and Non-Sclerosant Procedure for Chronic Venous Insufficiency

July 2, 2015 11:00 AM CT

12 month closure rates for the VenaSeal closure system comparable to radiofrequency ablation

DUBLIN -- July 2, 2015 -- Medtronic plc (NYSE: MDT) today announced the twelve-month results of the VeClose pivotal study, which demonstrated the safety and effectiveness of the VenaSeal(TM) closure system for the treatment of incompetent greater saphenous veins with a 96.8 percent closure rate. The results were presented by National Principal Investigator, Nick Morrison, M.D., Morrison Vein Institute, Scottsdale, Ariz., at the European Venous Forum 2015 in St. Petersburg, Russia.

The VenaSeal closure system is a unique, minimally invasive, non-tumescent, non-thermal and non-sclerosant procedure that uses an advanced medical adhesive to close the diseased vein in patients with symptomatic venous reflux disease. Unlike other treatments, the VenaSeal closure system does not require tumescent anesthesia, allowing patients to return to their normal activities following the procedure. The VenaSeal procedure also eliminates the risk of nerve or other heat-related injury associated with thermal-based procedures, and may reduce the need for compression stockings post-procedure.[i],[ii],[iii],*

"The VenaSeal closure system provides patients with a minimally invasive procedure that eliminates the need for surgery, thermal ablation and tumescent anesthesia. As a result, patients are often able to quickly return to normal activities after the procedure," said Dr. Nick Morrison, National Principal Investigator for the VeClose study. "The results show sustained closure with VenaSeal closure system that is comparable to closure rates with radiofrequency at 12 months."

The 12 month results of the VeClose study demonstrated outcomes for the VenaSeal closure system comparable with the closure rates associated with the ClosureFast™ catheter and demonstrated non-inferiority of the VenaSeal closure system:[iv],[v]

- At three months, the complete closure of the great saphenous veins achieved in more than 98.9 percent of patients treated with the VenaSeal closure system compared to 95.4 percent of patients treated with the ClosureFast catheter, showing non-inferiority of VenaSeal ($p<.0001$).
- The closure rate at six months was 98.9 percent and 94.3 percent for the VenaSeal closure system and the ClosureFast catheter, respectively.
- At 12 months, closure rates were identical between the two treatment groups at 96.8 percent.
- Additionally, no serious adverse events were reported.

"The 12 month results of the VeClose trial demonstrates the durability of the system," said Mark Turco, M.D., Medical Director, Aortic and Peripheral Vascular, Medtronic. "This, combined with the improved patient comfort and reduced recovery times of the VenaSeal closure system, makes this a clinically-proven, patient-friendly treatment option for patients.[i],[ii],[iii] "

The VenaSeal closure system is currently approved in Australia, New Zealand, Canada, Europe, Hong Kong, and the United States, and more than 2,000 patients have been treated with the system.

In collaboration with leading clinicians, researchers, and scientists, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular diseases and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers worldwide.

About the VeClose Study
The VeClose U.S. pivotal clinical study was designed as a prospective, randomized, controlled, non-inferiority study that compared the safety and effectiveness of the VenaSeal(TM) closure system to that of the ClosureFast(TM) endovenous radiofrequency ablation catheter. Medtronic's ClosureFast catheter is designed to collapse and close enlarged leg veins. Two hundred and twenty-two patients with symptomatic refluxing great saphenous veins were enrolled in the trial, of which 108 were randomized to receive treatment with the VenaSeal closure system and 114 with the ClosureFast catheter.

About Chronic Venous Insufficiency

Chronic Venous Insufficiency (CVI) is a progressive, sometimes debilitating medical condition. It occurs when valves in the veins of the lower leg no longer function to push blood back to the heart. This allows blood to flow backward, or reflux resulting in enlarged, or varicose, veins. If left untreated, the condition can progress and, in severe cases, can result in lifestyle-limiting lower leg pain, swelling, skin damage and ulcerations.

ABOUT MEDTRONIC

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is the global leader in medical technology -- alleviating pain, restoring health and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.
- end -

---

[i] Almeida JI, Javier JJ, Mackay E, Bautista C, Proebstle TM. First human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. Journal of Vascular Surgery: Venous and Lymphatic Disorders 2013;1:174-180.

[ii] Almeida JI, Javier JJ, Mackay EG, Bautista C, Cher DJ, Proebstle TM. Two-year follow-up of first human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. Phlebology / Venous Forum of the Royal Society of Medicine 2014.

[iii] Proebstle TM, Alm J, Dimitri S et al. The European multicenter cohort study on cyanoacrylate embolization of refluxing great saphenous veins. Journal of Vascular Surgery: Venous and Lymphatic Disorders.

[iv] CLF study

[v] VeClose reference

* Some patients may benefit from the use of compression stockings post-procedure.

Contacts:
Krystin Hayward
Public Relations
+1-508-261-6512

Ryan Weispfenning
Investor Relations
+1-763-505-4626